

Serial No. 10/690,811

Attorney Docket No. 24-009-TB

REMARKS

In part 12 of the Office Action Summary, the Examiner has checked the box indicating that the JP priority document has been received from the International Bureau. However, the applicant filed a certified copy of the priority document on April 10, 2007, together with a priority claim, as the present application is a "bypass continuation" of the underlying PCT application and not a National Stage application. The PAIR system shows that the priority document was received. Applicant respectfully requests that the next communication from the Patent Office appropriately acknowledge receipt of the certified copy of the priority document.

Applicant respectfully requests reconsideration and allowance of the pending claims for at least the following reasons.

Claims 1-10 and 13 were rejected under 35 U.S.C. §102(b) as being anticipated by U.S. Patent No. 5,456,745 of Roreger *et al.* (Roreger). Claims 3, 6 and 13 have been canceled without prejudice or disclaimer. Regarding the remaining rejected claims 1, 2, 4, 5, and 7 – 12, this rejection is respectfully traversed for at least the following reasons.

Claim 1 has been amended to recite in summary an orally administered agent in which an edible polymer layer containing a drug is located between first and second water-swellaible gel-forming layers that are provided as outermost layers, that form a mask for at least one of a taste and a smell of the drug, and that, together with the edible polymer layer, facilitate a digestive tract release of the drug. This particular configuration is shown, for example, in Figs. 2 – 5 and is discussed on, for example, pages 23 – 28 and in the manufacturing examples discussion on pages 35 – 39 of the specification.

The teachings of Roreger do not contemplate or suggest, *inter alia*, an orally administered agent as recited in amended claim 1 in which an edible polymer layer containing a drug is located between first and second water-swellaible gel-forming layers that are provided as

Serial No. 10/690,811

Attorney Docket No. 24-009-TB

outermost layers, that form a mask for at least one of a taste and a smell of the drug, and that, together with the edible polymer layer, facilitate a digestive tract release of the drug.

Specifically, as discussed in the voluntary amendment filed on October 30, 2007, the teachings of Roreger are related merely to a flexible, hydrophilic gel film that is applied to the skin or a mucous membrane. The Examiner should note that the above underlined features recited in claim 1 are features that are now recited in the body, rather than the preamble, of the claim.

In addition, Roreger does not disclose that the content of the water-swellaable gel-forming agent is 15 to 70wt%, and the content of the film-forming agent is 30 to 85wt% as recited in claims 1 and 13. The content of the film-forming agent in Roreger is less than 30 wt%. For example, in EXAMPLE 19 in the Roreger patent, the content of the film-forming agent (13g polyvinylalcohol, 35g polyvinyl pyrrolidone and 15+2.5g Na-carboxymethylcellulose) is 65.5g in 330.54g, or 19.8wt%.

Accordingly, applicant respectfully submits that Roreger is deficient in its teachings for the above noted reasons.

Further, as discussed at length in the voluntary amendment filed with an RCE on October 30, 2007, the preamble of claim 1 distinguishes the presently claimed invention by defining an *orally administered agent*, which area of technology is unique and presents significantly more difficulties compared to, for example, the flexible, hydrophilic gel film that is applied to the skin or mucous membrane, such as that disclosed in Roreger. Therefore, applicant again respectfully submits that Roreger does not disclose an *orally administered agent* as recited in claim 1.

At least for the foregoing reasons, applicant respectfully submits that the orally administered agent recited in claim 1 is patentably distinguishable over the teachings of Roreger.

Serial No. 10/690,811

Attorney Docket No. 24-009-TB

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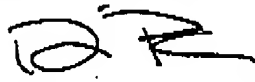
Therefore, applicant respectfully requests that the examiner reconsider and withdraw his rejection under 35 U.S.C. 102(b) of claim 1, as well as dependent claims 2, 4, 5 and 7 - 12.

The Examiner should note that new claims 14 - 21 have been added and are directed to a gel-forming composition. Examination and allowance of these new claims is respectfully requested. Support for new claims 14 and 15 may be found, for example, on page 12, lines 15 - 26. Support for new claim 16 these new claims may be found, for example, on page 26, lines 8 - 14. Support for new claims 17 - 21 may be found, for example, on page 25, line 6 to page 26, line 5.

While it is believed that the present response is a complete and proper response to the Office Action mailed February 7, 2008, the Examiner is invited to contact the undersigned at the below listed number to resolve any outstanding issues.

Please charge any unforeseen fees to deposit account No. 50-1147.

Respectfully submitted,



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